DETAILED ACTION

Status of the claims

1. Claims 1-9, 12, 14 are pending and subject to the examination. Claims 10, 11, and 13 were cancelled in the preliminary amendment submitted on the 08/23/2006 with the initial filing of the application.

Claim objections

2. Claims 1, 5, 6, 12 and 14 are objected to because of the following informalities: they miss the indefinite article at the beginning of the claim (e.g. *An* assay..._). Appropriate correction is required.

3. Claim 7 is objected to for stating "interleukin-12 antibody". Amendment to read "*anti*-interleukin-12 antibody" would be remedial.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an agent, or a pharmaceutical composition comprising it that is identified by a selection method comprising contacting interleukin-23 and/or interleukin-12 with a corresponding interleukin receptor in the absence and in the presence of a candidate compound which is expected to modulate the interaction of said interleukin with said receptor for a sufficient period of time so that a complex between said interleukin and said receptor can be formed. The claims are thus drawn to a genus of compounds that are allegedly defined by a result to be achieved, with no defining structural characteristics or relationships between structure and function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification provides a description of assays to performed, there is no disclosure of any specific oligopeptides, polypeptides, proteins, antibodies, mimetics, small molecules, or libraries would selectively modulate the interactions. An assay is not a description of the products identified thereby.

The courts held that an adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively

inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.").

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 is indefinite because part (a) specifies that the candidate compound *is* present, whereas part (d) says it might *not* have been present. While it is clear that applicants intend a control, the steps as written are inconsistent.

8. Claims 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because they are not adequately described and thus a meaningful and comprehensive search cannot be carried out. Thus, the meets and bounds of the claims could not be established.

Claim 14 is indefinite because it is unclear how step b), in the situation that the receptor is saturated, would allow the determination of the IL-12 binding in step (c).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, 5, 6, 7, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gately et al. (U.S. Pat. No. : 5,853,721- cited by the Applicant)

Gately et al. teach monoclonal antibody, 2B10, to the human IL-12 receptor β subunit and a combination of monoclonal antibodies to the human IL-12 receptor β

subunit , 2B10+2*4E6, which inhibits IL-12 bioactivity (col. 7, lines 11-18). Also taught are therapeutical (pharmaceutical) compositions formulated for parenteral administration (col. 8, lines 4-13), as well as method of detecting IL-12 receptor comprising the steps comprises contacting a sample which contains the subject cells with substances capable of forming complexes with the IL-12 receptors so as to form cellular complexes between the substances and the IL-12 receptors, and detecting such cellular complexes (col. 8, lines24-30, examples 6, 12, 13, 25 and 26). The labeled IL-12 antibody is taught in example 14. All the elements of the kit claimed in the instant application were presented in the examples cited above and in Example 28 from Gately et al. since the instructions are not considered patentable subject matter. Thus, the claims 1, 2, 5, 6, 7, 9 and 12 are anticipated by Gately et al.

11. Claims 1, 2, 3, 4, 5, 6, 8, 9, 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Benson et al. (U.S. Pat. No.: 7,247,711).

Benson et al. teach Ig derived proteins including antibody and antagonist or receptor fusion proteins that block the binding of IL-23 to at least one of its receptors (e.g., but not limited to, IL-23 receptor and/or IL-12 beta 1 receptor) including immunoglobulins, receptor fusion proteins, cleavage products and other specified portions and variants thereof, as well as anti-IL-23p40 Ig derived protein compositions, and discloses compositions, formulations, methods, devices and uses of such anti-IL-23p40 Ig derived proteins, including for therapeutic and diagnostic uses (col. 3, lines 1-53). The proteins provided are used for modulation of the effects of IL-23 (col. 6, lines 15-23). Compositions and formulations comprising the blocking peptides are disclosed

at col. 33 line5 to col. 34, line 59. The elements of the kit claimed in the claim 6 of the instant application and the methods described in the claim 1 and claim 14 of the instant application are disclosed by Benson et al. in example 3 of the U.S. Pat. No.: 7,247,711, since the instructions are not considered patentable subject matter.

Thus, thus the claims 1, 2, 3, 4, 5, 6, 8, 9, 12 and 14 are anticipated by Benson et al.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gately et al. (U.S. Pat. No. : 5,853,721) in view of Gubler et al. (EP 123597, 09/25/2002-cited by the Applicant).

The claims are drawn to a method for identifying an agent that modulates the interaction between interleukin-23 and/or interleukin-12 with a corresponding interleukin receptor wherein the receptor is fused to an immunoglobulin or a fragment thereof or to a kit for identifying an agent that modulates the said interaction comprising an interleukin receptor fused to an immunoglobulin or a fragment thereof.

The teachings of Gately et al. were presented supra. Gately et al. does not explicitly teach the interleukin receptor fused to an immunoglobulin or a fragment thereof.

Gubler et al teach a method of using IL-12 Receptor fusion proteins with the F_C part of IgG, in an assay to detect binding between IL-12 and the IL-12R or IL-12R/Fc fusion protein (abstract, [38-41] and [70-71]; examples 5 and 9).

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to combine the teachings of Gately et al. and Gubler et al. to set up an assay for modulators of the interaction between the IL-23 or IL-12 and their respective receptors with a reasonable expectation of success. A person of ordinary

skill in the art is always motivated to use the technical means at his disposal to improve an assay or to obtain better, faster and easier the results sought after. Hence the motivation to combine the teachings since the fusion protein would have been easier to detect because of the IgG part.

16. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gately et al. (U.S. Pat. No. : 5,853,721) in view of Parham C et al. (J Immunology, 168, 5699-5708, 2002-cited by the Applicant).

The teachings of Gately et al. were presented supra. Gately et al. does not teach an assay wherein in the receptor is IL-23 receptor and the interleukin is IL-23.

Parham et al teach that the IL-12 and IL-23 cytokines are functionally related. Parham et al describe the binding of both ligands to their different receptors components, showing that IL-12-R-beta-1 binds both IL-12 p40 and IL-23 p19, IL-12-R-beta-2 binds IL-12 p35 only and IL-23-R is IL-23 p19 specific. Both Il-12 and IL-23 have similar effects on cellular signaling (p. 5699, right col., first full paragraph; p. 5701, right col. from subheading "Structure of IL-23R" to p. 5703, left col. line 23; figures 2-4; p. 5706, first 7 lines from the Discussion section).

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used the method of Gately et al., that is able to determine modulators of the IL-l2/IL- 12R interaction, to identify modulators for IL-23/IL-23R interactions with a reasonable expectation of success because Parham et al. provides the knowledge that IL-12 and IL-23 are closely related and even partly use the

same receptor. The motivation to do so is implicitly present in Parham et al, since the cytokines partially share the same receptor.

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
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